K080580

AXELGAARD MANUFACTURING CO., LTD.

JUN 18 2008

510 Summary

(As required by 21CFR section 807.92(c)

Submitter Information

Name: Axelgaard Manufacturing Co., Ltd.

Address: 520 Industrial Way
Fallbrook, CA 92028

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Contact Person: Dan Jeffery

Date Prepared: Revised June 16, 2008

Device Information

Device Name: Comfort Iontophoresis Electrodes
Buffered Iontophoresis Electrode Treatment Kit

Common Name: Iontophoresis Electrodes

Classification Name: Device, Iontophoresis, Other Uses (per 21 CFR section 890.5525)

Predicate Devices

Based on technical, functional, and physical comparisons, the Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) are substantially equivalent to the following legally marketed devices of North Coast Medical and Dynatronics. Axelgaard Manufacturing Co, Ltd has manufactured this product for both North Coast Medical and Dynatronics for the past two years.

Trade Name	Manufacturer/Distributor	510(k) Number
Buffered Iontophoresis Drug Delivery Electrodes	North Coast Medical	K052019
Dynatron Ion	Dynatronics	K060814

Device Description

Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) consist of an active drug delivery electrode and a passive return electrode. These electrodes are designed for one use on a single patient for the local administration of ionic drug solutions into the body for medical purposes. There are four sizes and shapes of drug delivery electrodes to accommodate placement on various locations on the body. The size of the return electrode is the same for all drug delivery electrode sizes as the maximum delivery of 80 milliamp-minutes is the same regardless of size. **Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit)** have technological characteristics equivalent to those of the predicate devices, including comparable design, materials, multiple shapes and sizes of active drug delivery electrodes, and equivalent packaging and labeling.

Intended Use

Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.

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Substantial Equivalence Comparison

1. Predicate device names:
   A. North Coast Medical Buffered Iontophoresis Electrodes
   B. Dynatron Ion

2. Predicate 510(k) number:
   A. K052019
   B. K060814

3. Comparison with predicate:

Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) are equivalent to North Coast Medical Buffered Iontophoresis Electrodes (previously cleared under K0502019) and Dynatron Ion (previously cleared under K060814). The tables below list the similarities, equivalencies, and differences between the proposed and predicate devices.

Similarities

Item	Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) Proposed Device	North Coast Buffered Iontophoresis Electrodes Predicate Device (K052019	Dynatron Ion Predicate device (K060814)
Intended use	Iontophoresis is indicated for the administration of soluble salts or other drugs into the body for medical purposes and can be used as an alternative to hypodermic injection.	Iontophoresis is indicated for the administration of soluble salts or other drugs into the body for medical purposes and can be used as an alternative to hypodermic injection.	Iontophoresis is indicated for the administration of soluble salts or other drugs into the body for medical purposes and can be used as an alternative to hypodermic injection.
Target population	Medical professionals with patients requiring iontophoresis treatment.	Medical professionals with patients requiring iontophoresis treatment.	Medical professionals with patients requiring iontophoresis treatment.
Design	Shapes: Small Square, Butterfly, Medium Square, Large Square, Return Electrode.	Shapes: Small Square, Butterfly, Medium Square, Large Square, Return Electrode.	Shapes: Small Square, Butterfly, Medium Square, Large Square, Return Electrode.
Materials	Buffering Agent – Silver/SilverChloride (Ag/AgCl). Conductive layer on polyester.	Buffering Agent – Silver/SilverChloride (Ag/AgCl). Conductive layer on polyester.	Buffering Agent – Silver/SilverChloride (Ag/AgCl). Conductive layer on polyester.
Chemical safety	Electrodes backed with non-irritating adhesive.	Electrodes backed with non-irritating adhesive.	Electrodes backed with non-irritating adhesive.
Anatomical sites	For epidermal use (various locations).	For epidermal use (various locations).	For epidermal use (various locations).
Energy used/delivered	Not to exceed 80mA-minutes total dosage.	Not to exceed 80mA-minutes total dosage.	Not to exceed 80mA-minutes total dosage

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Item	Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) Proposed Device	North Coast Buffered Iontophoresis Electrodes Predicate Device (K052019	Dynatron Ion Predicate device (K060814)
Compatibility with other devices	Designed for use with iontophoresis devices only.	Designed for use with iontophoresis devices only.	Designed for use with iontophoresis devices only.
Where used	Hospitals, medical clinics.	Hospitals, medical clinics.	Hospitals, medical clinics.
Electrical safety	Does not have electrode wires.	Does not have electrode wires.	Does not have electrode wires.
Electrode Fill Volume (treatment fluid volume)	Small Square (1.5 to 2.0cc) Butterfly (2.0 to 2.5cc) Medium Square (2.5 to 3.0cc) Large Square (4.0 to 4.5cc)	Small Square (1.5 to 2.0cc) Butterfly (2.0 to 2.5cc) Medium Square (2.5 to 3.0cc) Large Square (4.0 to 4.5cc)	Small Square (1.5 to 2.0cc) Butterfly (2.0 to 2.5cc) Medium Square (2.5 to 3.0cc) Large Square (4.0 to 4.5cc)

Equivalencies

Item	Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) Proposed Device	North Coast Buffered Iontophoresis Electrodes Predicate Device (K052019	Dynatron Ion Predicate device (K060814)
Design (Electrode Size)	Electrode Size – Small Square (2.75"x2.75") Butterfly (3.75"x3.38") Medium Square (3.25"x3.25") Large Square (3.50"x3.50") Return Electrode (2.20"x1.82")	Electrode Size – Small Square (2.75"x2.75") Butterfly (3.75"x3.38") Medium Square (3.25"x3.25") Large Square (3.50"x3.50") Return Electrode (2.20"x1.82")	Electrode Size – Small Square (2.75"x2.75") Butterfly (3.75"x3.38") Medium Square (3.25"x3.25") Large Square (3.50"x3.50") Return Electrode (2.20"x1.82")
Design (Active Area)	Active Area – Small Square (7.6 cm^2) Butterfly (8.3 cm^2) Medium Square (11.4 cm^2) Large Square (18.1 cm^2) Return Electrode (25.5 cm^2)	Active Area – Small Square (7.6 cm^2) Butterfly (8.3 cm^2) Medium Square (11.4 cm^2) Large Square (18.1 cm^2) Return Electrode (25.5 cm^2)	Active Area – Small Square (7.6 cm^2) Butterfly (8.3 cm^2) Medium Square (11.4 cm^2) Large Square (18.1 cm^2) Return Electrode (25.5 cm^2)
Maximum Current	4 mA	4mA	4mA
Maximum Dosage	80 mA-minutes	80 mA-minutes	80 mA-minutes
Materials	Reservoir Layer – Cotton Blend	Reservoir Layer – Cotton Blend	Reservoir Layer – Cotton Blend

Differences

There are no differences other than the packaging and labeling information specific to the distributing company.

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Discussion

In comparing the **Comfort Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit)** (proposed device) to the North Coast Medical, North Coast Buffered Iontophoresis Electrodes (predicate device), and the Dynatronics, Dynatron Ion (predicate device), it must be noted that there are no product differences since Axelgaard Manufacturing Co., Ltd. manufactures both these electrodes. Additionally, the packaging/labeling differences are not substantial enough to deny equivalence between the three products.

The intended use, operation, and target population of the three products are almost identical. Also, the product shapes are the same, so they can conform to the same anatomical locations. The product size is the same so there will be no difference with adhesion and coverage of the affected area. Since the same buffering agents are used, as well as non-irritating backing, conduction and adhesion of the electrodes shall be safe as they are the same. The reservoir layer is composed of the same materials. Finally, the products are applied identically, and they use comparable power sources.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2008

Axelgaard Manufacturing Company, Limited
% Mr. Dan P. Jeffery
President
520 Industrial Way
Fallsbrook, California 92028-2244

Re: K080580
Trade Name: Comfort Iontophoresis Electrodes / Buffered Iontophoresis Electrode Treatment Kit
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class III
Product Code: EGJ
Dated: April 28, 2008
Received: April 30, 2008

Dear Mr. Jeffery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AXELGAARD MANUFACTURING CO. LTD.

Indications for Use

http://www.fda.gov/cdrh/ode/indicate.pdf

510K Number: **K080580**

Device Name Comfort Iontophoresis Electrodes
Buffered Iontophoresis Electrode Treatment Kit

Indications for Use:
Iontophoresis is indicated by clinicians for the administration of soluble salts or other drugs into the body for medical purposes and can be used as an alternative to hypodermic injection.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(As required by 21CFR section 807.92(c))

Neil R. Ogden for mam

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080580